

the claim. Claim 39 is not directed to any compound that is a non-peptide, but is directed to a non-peptide iodine-containing intravenous contrast agent. The specification does provide basis for a non-peptide iodine containing intravenous contrast agent since the specification clearly describes the claimed class by naming numerous specific suitable contrast agents described, for example, on page 6, lines 7 to 9 from the bottom of the page. Similarly, the remaining terms, i.e., "non-polymer," and "non-ionic," should also not be read apart from the remainder of the claim in which they appear. In each case sufficient basis is present in the specification that one of ordinary skill in the art, upon reading the specification and the examples of contrast agents, would have recognized possession of the claimed classes, including those described by negative limitations.

Within the art of diagnostic imaging, contrast agents that are ionic and contrast agents that involve polymers and peptides are well known. Yet, Applicants' specification clearly provide examples of iodine-containing contrast agents which are non-ionic, or non-polymer or non-peptidic. Thus, one of ordinary skill in the art would recognize the possession of such subgeneric concepts upon reading Applicants' disclosure.

The Office Action cites *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983), for the position that any negative limitation must have basis in the original disclosure. While that is correct; *Grasselli* does not require the literal support for negative limitations. As discussed in MPEP § 2173.05(i), the "lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support." *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1993). "The mere absence of a positive recitation is not basis for an exclusion." See MPEP § 2173.05(i). The test is whether one of ordinary skill in the art would have, upon reading the specification, recognized possession of the claimed classes, including those described by negative limitations. Applicants submit that in this case, basis for the claims, including the negative limitations, exists.

Reconsideration is respectfully requested.

Rejection of Claim 18 Under 35 U.S.C. § 102(e)

The Office Action alleges that claim 18 is anticipated by Galkin.

Galkin alleges the possibility of the use of contrast agents in mammography, but not that such was done. Galkin teaches that the desirable characteristics of such contrast agents is

that they have a “preferential affinity for the cancer tissue.” See column 4, lines 52-54. Galkin, however does not name even one single contrast agent. Nowhere does Galkin teach or suggest the use of the claimed nonspecific, extracellular or urographic contrast agents in mammography.

Rejection of Claims 18-45 Under 35 U.S.C. § 103

The claims are rejected over the combination of either of two primary references and six secondary references. However, these references, alone or in combination, do not provide motivation that would lead a skilled artisan toward the claimed invention.

The Office Action alleges that both Galkin (discussed above) and Nitecki teach the use of a contrast agent for mammography. Nitecki mentions mammography among a whole variety of applications, and mentions the use of contrast agents among a whole variety of possibilities, but only does so in a general sense. No specific teaching or suggestion, e.g., no example, is provided which would enable one of ordinary skill in the art to perform mammography with the use of a contrast agent. Neither of these references provides an enabling disclosure.

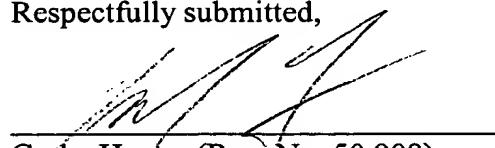
Additionally, with respect to dependent claims directed to specific contrast agents, nowhere does Nitecki teach or suggest that any of the claimed contrast agents would be suitable for mammography. Nitecki is specifically directed to a “new x-ray contrast media,” i.e., “iodine-containing peptides,” which are not claimed in the present invention. See column 2, lines 58-66. Nitecki specifically teaches that x-ray media that are used for angiography, or iodized macromolecular contrast media, or dextran derivatives, or iodine-containing polyamines are not suitable. See column 2, lines 35-61.

Both primary references suggest a new type of contrast agent is needed to achieve the variety of uses listed (in Galkin’s case, not one specific suitable contrast agent is taught), but does not point to any particular contrast agent that is used in mammography.

The secondary references each only teach specific contrast agents without any motivation for their use in mammography. The claimed invention is therefore not obvious from the teachings of the cited references.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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